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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte AARON W. JANKE,
MARY LEE COLE, RONALD W. HEIL, JR.,
JEFFREY T. BARTIG, GARY W. GOEBEL, DOUGLAS A. HEITKAMP,
and RANDALL M. PETERFESO

Appeal 2010-002399
Application 10/650,207
Technology Center 3700

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134 involves claims to an electrode implantable in the heart. The Examiner entered six rejections for obviousness.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse two of the rejections, but affirm the other four.

STATEMENT OF THE CASE

Claims 1-8 and 16-19 stand rejected and appealed (App. Br. 4).[2] Claims 1 and 16, the independent claims, are representative and read as follows:

> 1. A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising:
>
> an electrode tip;
>
> a mesh screen disposed at a distal end of the electrode tip;
>
> a surface at the distal end of the electrode tip;
>
> a helix disposed within said electrode, said helix adapted for travel along a radial axis of the electrode through said surface, the helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient;
>
> a guiding mechanism for directing movement of the fixation device during travel; and
>
> a movement assembly, said movement assembly for providing movement to said fixation device.
>
> 16. A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising:
>
> an electrode tip;
>
> a mesh screen disposed at a distal end of the electrode tip;
>
> a surface at the distal end of the electrode tip; and

[2] Appeal Brief entered April 27, 2009.

> a fixation helix disposed within said electrode, said fixation helix adapted for travel along a radial axis of the electrode through said surface, the fixation helix including a non-soluble insulating material coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient.

The Examiner cites the following documents as evidence of unpatentability:

Rockland et al.	US 4,010,758	Mar. 8, 1977
Grassi	US 4,624,265	Nov. 25, 1986
Bisping	US 4,886,074	Dec. 12, 1989
Dutcher et al.	US 5,217,028	Jun. 8, 1993
Jammet	US 5,447,534	Sep. 5, 1995
Vachon	US 5,531,780	Jul. 2, 1996
Altman	US 5,551,427	Sep. 3, 1996
Ocel et al.	US 5,837,006	Nov. 17, 1998
Hoffmann et al.	US 5,902,329	May 11, 1999

The following rejections are before us for review:

(1) Claims 1-5, 7, 8, and 16-19, rejected under 35 U.S.C. § 103(a) as obvious over Bisping and Dutcher (Ans. 4-6);[3]

(2) Claims 1-5, 7, 8, and 16-19, rejected under 35 U.S.C. § 103(a) as obvious over Bisping and Rockland in view of Altman or Hoffman (Ans. 7-9);

(3) Claims 1-3, 7, 8, and 16-19, rejected under 35 U.S.C. § 103(a) as obvious over Grassi and Dutcher (Ans. 10-12);

(4) Claims 1-3, 7, 8, and 16-19, rejected under 35 U.S.C. § 103(a) as obvious over Grassi and Rockland in view of Altman or Hoffman (Ans. 13-15);

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[3] Examiner's Answer entered August 6, 2009.

(5) Claims 4 and 5, rejected under 35 U.S.C. § 103(a) as obvious over "modified Grassi rejected above" in view of Bisping, Jammet, or Ocel (Ans. 16); and

(6) Claim 6, rejected under 35 U.S.C. § 103(a) as obvious over "either modified Bisping or either modified Grassi as applied to claim 1 above" in view of Ocel or Vachon (Ans. 16).

OBVIOUSNESS -- BISPING AND DUTCHER

ISSUE

In rejecting claims 1-5, 7, 8, and 16-19 as obvious over Bisping and Dutcher, the Examiner concluded that an ordinary artisan would have considered it obvious to incorporate the drug-containing coating and mesh of Dutcher's heart-implantable electrode into Bisping's heart-implantable electrode (Ans. 4-5).

Appellants contend that Dutcher does not disclose a drug-containing insulating material that is coated onto the helical element of its electrode, but instead discloses a drug-containing plug around which the helical element is wrapped (App. Br. 11-12). In particular, Appellants argue, "the plug 138 is merely held within the rear inner area of the helix. The plug 138 itself does not conform to or coat the helix outer surface" (Reply Br. 2).[4]

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether a preponderance of the evidence of record supports the Examiner's determination that an ordinary artisan would have been prompted by Dutcher to include a coating having the features recited in claims 1 and 16 on Bisping's device.

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[4] Reply Brief entered October 6, 2009.

FINDINGS OF FACT ("FF")

1. Bisping discloses an "implantable electrode type lead assembly of the flexible type which is particularly adapted for implantation in the cardiac muscle for applications such as use with a pacemaker. The lead assembly has an electrode head which includes a fixation spiral for implantation into tissue" (Bisping, abstract; *see also* Figures 1 and 4).

2. Dutcher discloses a "bi-polar cardiac lead for transmitting electric current to the heart" (Dutcher, abstract).

3. Figure 5 of Dutcher, reproduced below, is a side view of Dutcher's cardiac lead:

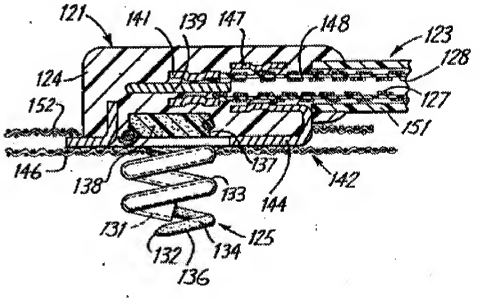

Figure 5 shows helical electrode 125, which is "a rigid helical wire 131 terminating in a pointed or sharpened end 132. A sheath 133 of non-electrical conductive material, such as medical grade silicone rubber, covers

the helical wire 131 except for about the end one half turn portion 134 thereof" (*id.* at col. 3, ll. 56-60).

4. Figure 5 of Dutcher also shows:

> [T]he mid-section of the inner side of head 124 has a cylindrical recess or pocket 137 accommodating a plug 138 impregnated with a drug to elution [sic] at the stimulation site. . . . The inner end section 126 of wire 131 is turned around the outer circumference of plug 138 to locate plug 138 in co-axial alignment with helical electrode 125. The drug will be dispensed from the outer surface of plug 138 to the heart tissue as plug 138 positioned in contacting relationship with the heart tissue.

(*Id.* at col. 4, ll. 46-56.)

PRINCIPLES OF LAW

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992).

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question, but also reaffirmed the importance of determining "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue." *Id.* at 418 (emphasis added).

Ultimately, therefore, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

ANALYSIS

We agree with Appellants that the teachings of Bisping and Dutcher do not support the Examiner's prima facie case.

Claim 1 recites an electrode for implantation on or about the heart, the electrode having a "helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient." Claim 16 similarly requires the active ingredient-containing insulating material to be "coated on at least a portion of [the helix's] outer surface so as to conform to the outer surface of the helix."

As seen in Figure 5 of Dutcher, while the helical wire element of Dutcher's electrode has an insulating coating or sheath 133 (FF 3), the active ingredient-containing portion of the electrode is drug plug 138 (FF 4). Rather than being coated with the drug, however, the wire constituting Dutcher's helix is wrapped around drug plug 138 (Dutcher, col. 4, ll. 50-53 ("[t]he inner end section 126 of wire 131 is turned around the outer circumference of plug 138")).

Given these teachings, we are not persuaded that an ordinary artisan would have viewed Dutcher as teaching or suggesting the drug plug coated on the helix in the manner recited in claims 1 and 16, nor are we persuaded that the drug plug conforms to the outer layer of the helix, since wrapping the wire around the plug results in the plug only being on the inner part of the helix.

The Examiner argues, alternatively, that when Dutcher's device is deployed, the active ingredient in the plug will migrate along the insulated

coating, the result being that Dutcher's device at that point has an insulating coating on the helix that includes an active ingredient (Ans. 17).

The Examiner points to no teaching in Dutcher, however, suggesting that the drug moves in this way. To the contrary, Dutcher discloses that the "drug will be dispensed from the outer surface of plug 138 to the heart tissue as plug 138 [is] positioned in contacting relationship with the heart tissue" (Dutcher, col. 4, ll. 53-56).

In sum, we agree with Appellants that the Examiner has not adequately explained why an ordinary artisan viewing the teachings in the cited references would have been prompted to prepare an electrode having the coated helix recited in claims 1 and 16. Accordingly, we reverse the Examiner's rejection of those claims, as well as their dependent claims 2-5, 7, 8, and 17-19, as obvious over Bisping and Dutcher.

OBVIOUSNESS --

BISPING, ROCKLAND, ALTMAN, AND HOFFMAN

ISSUE

Claims 1-5, 7, 8, and 16-19 stand rejected under 35 U.S.C. § 103(a) as obvious over Bisping and Rockland in view of Altman or Hoffman (Ans. 7-9). Based on the references' teachings, the Examiner concludes that an ordinary artisan would have considered it obvious to incorporate the mesh from Rockland's heart-implantable electrode, and the drug-containing coating used in either Altman's or Hoffman's heart-implantable devices, into Bisping's device (*id.* at 7-8).

Appellants contend that an ordinary artisan would not have applied Altman's teachings to Bisping because, rather than stimulating the heart muscle like Bisping's electrode, Altman's device was intended to inhibit the

heart muscle activity at arrhythmogenic sites (App. Br. 12-13). Appellants further argue that Hoffman teaches away from applying its hydrogel composition as an insulating coating (*id.* at 13).

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether the evidence of record supports the Examiner's position that an ordinary artisan would have been prompted by either Altman or Hoffman to include a coating having the features recited in claims 1 and 16 on Bisping's device.

FINDINGS OF FACT

5. Altman discloses "implantable devices for the effective elimination of an arrhythmogenic site from the myocardium" (Altman, abstract).

6. Specifically, Altman discloses that "[b]y inserting small biocompatible conductors, insulators, and/or combinations thereof into the heart tissue at the arrhythmogenic site, it is possible to effectively eliminate the arrhythmogenic effects of a portion of the tissue from the electric field and current paths within the heart" (*id.* at col. 9, ll. 39-44).

7. Altman's devices include a corkscrew-shaped helix that is inserted into the heart tissue, the helix being "constructed with a rigid core material 58 coated or covered with an insulative controlled release matrix 60. Matrix 60 is a drug diffusion polymer system for the sustained release of drugs" (*id.* at col. 10, ll. 27-30).

8. Altman discloses that its devices can deliver a number of different types of drugs, including "anti arrhythmic agents, anti thrombogenic agents, angiogenic factors, and/or steroidal anti inflammatory agents over an extended period of time directly to endocardial regions" (*id.* at col. 6, ll. 64-67).

9. Altman notes that steroidal anti-inflammatory agents had been previously incorporated into cardiac stimulation leads "to limit tissue response to the implanted lead, and to maintain the viability of the cells in the region immediately surrounding the implanted device" (*id.* at col. 6, ll. 6-9).

ANALYSIS

We are not persuaded that the evidence fails to support the Examiner's obviousness determination. The Examiner contends that an ordinary artisan would have been prompted to use either Altman's or Hoffman's coating on Bisping's device "to allow the fixation to still be inserted into the heart with out [sic] causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation due to the helix" (Ans. 8).

Appellants do not directly address the Examiner's position regarding the desirability of administering anti-inflammatory agents to heart tissue via affixed helical devices, but instead argue that "there appears to be no motivation or reason to apply any of Altman's or Hoffman's discussions to the lead of Bisping, since they are used for generally different purposes" (App. Br. 13).

In particular, Appellants note, "Bisping gives no indication of a need for any of the Objects of Invention described in Altman at col. 6, line 20 - col. 7 line 3, where the Altman disclosure discusses different purposes of the device to treat arrythmogenic sites" (*id.*). Thus, Appellants argue, "[m]erely because Altman discusses a helix shape for the arrythmogenic treatment device does not mean that his disclosure applies to a helix used for a

completely different purpose, such as the Bisping helix, which is used as a fixation device to hold an electrode in place" (*id.*; *see also* Reply Br. 3-4).

The Examiner has the better position, in our view.

We acknowledge Altman's disclosure that its devices are used to decrease or eliminate cardiac activity at problematic sites in the heart muscle (FF 5-6). We also acknowledge that, in contrast, Bisping's helix-containing electrode is explicitly described as being part of a pacemaker, that is, a heart stimulating device (FF 1).

However, as the Examiner points out, Altman discloses that its drug-containing coating allows its device to administer anti-inflammatory drugs directly to the heart (FF 8). Altman further discloses that anti-inflammatory drugs are not only useful on its own anti-arrhythmogenic devices, but also on heart-stimulating cardiac leads, to limit undesirable tissue response to the implants (FF 9).

Thus, we agree with the Examiner that an ordinary artisan, advised by Altman that it was desirable for heart-stimulating implants to include anti-inflammatory agents, and also advised by Altman that its drug-containing coating imparts anti-inflammatory properties to helical heart-affixing devices, would have been prompted to coat at least a portion of Bisping's heart-affixing helix with Altman's coating. Thus, because an ordinary artisan would have recognized that an anti-inflammatory coating would have been useful in heart-stimulating devices such as Bisping's, as well as anti-arrhythmogenic devices, Appellants' arguments do not persuade us that the Examiner failed to make a prima facie case of obviousness.

Accordingly, we affirm the Examiner's rejection of claims 1-5, 7, 8, and 16-19 as obvious over Bisping, Rockland, and Altman.

OBVIOUSNESS -- GRASSI AND DUTCHER

Claims 1-3, 7, 8, and 16-19 stand rejected as obvious over Grassi and Dutcher (Ans. 10-12). This rejection is similar to the rejection over Bisping and Dutcher, except that the Examiner cites Grassi instead of Bisping as teaching a helical/corkscrew device for affixing the electrode into the cardiac muscle (*id.* at 10). As with the previous rejection, the Examiner cites Dutcher as teaching the insulating active ingredient-containing coating recited in claims 1 and 16.

For the reasons discussed above, we are not persuaded that Dutcher teaches or suggests an active ingredient-containing coating with the features required in claims 1 and 16. Accordingly, we reverse the Examiner's obviousness rejection of those claims, and their dependent claims 2, 3, 7, 8, and 17-19, over Grassi and Dutcher.

OBVIOUSNESS --
GRASSI, ROCKLAND, ALTMAN, AND HOFFMAN

Claims 1-3, 7, 8, and 16-19 stand rejected as obvious over Grassi and Rockland in view of Altman or Hoffman (Ans. 13-15).

This rejection is similar to the earlier rejection over Bisping and Rockland in view of Altman or Hoffman, except that the Examiner cites Grassi instead of Bisping as teaching a helical/corkscrew device for affixing the electrode into the cardiac muscle (*id.* at 13). As with the earlier rejection, the Examiner cites Rockland to show the obviousness of using mesh on heart-affixing electrodes, and either Altman or Hoffman to show the obviousness of an insulating active ingredient-containing coating on such devices (*id.* at 13-14).

Similar to the earlier rejection, Appellants' argument is that an ordinary artisan would not have applied Altman's teachings to Grassi's device because the two references' devices are used for different purposes (App. Br. 15; *see also* Reply Br. 4-5). However, as discussed above, given that an ordinary artisan would have understood from Altman that anti-inflammatory coatings were useful on heart-stimulating implantable devices, we are not persuaded that the artisan would have lacked impetus for applying Altman's coating to Grassi's device.

Accordingly, we affirm the Examiner's rejection of claims 1-3, 7, 8, and 16-19 as obvious over Grassi and Rockland in view of Altman.

OBVIOUSNESS --

GRASSI, BISPING, JAMMET, AND OCEL

Claims 4 and 5 stand rejected as obvious over "either modified Grassi rejected above" in view of Bisping, Jammet, or Ocel (Ans. 16). Claims 4 and 5 read as follows:

> 4. The distal tip electrode as recited in claim [1, wherein said movement assembly comprises a piston and a base, and] wherein the piston has a slot therein, and the base further comprises a knob, said slot for mating with said knob.
>
> 5. The distal tip electrode as recited in claim 4, wherein the slot is mated with said knob to form a stop mechanism for said fixation device.

The Examiner finds that "[m]odified Grassi discloses the claimed invention except for the knob and slot mating with the knob to form a stop mechanism" and cites Bisping, Jammet, or Ocel to meet that feature (*id.*). Based on the references' teachings, the Examiner concludes that an ordinary artisan would have considered it obvious

> to modify the heart lead as taught by the modified Grassi, with a knob and slot mating with the knob to form a stop mechanism as taught by Bisping, Jammet, or Ocel since it was known in the art that heart leads use a knob and slot mating with the knob to form a stop mechanism to provide the predictable results of preventing the helix from being retracted further into the lead and causing damage to the lead.

(Ans. 16.)

Appellants argue that claims 4 and 5 are unobvious for the reasons advanced with respect to claim 1 (App. Br. 16). Moreover, Appellants argue, the Examiner "has provided insufficient motivation to modify the cited reference. Appellant notes that the mere fact that a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination" (*id.* (citing *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990); MPEP § 2143.01)).

Appellants' arguments do not persuade us that the Examiner failed to make a prima facie case of obviousness. As discussed above, we are not persuaded that the Examiner's prima facie case was lacking with respect to claim 1.

As to the motivation issue, the Examiner has provided evidence, undisputed by Appellants, that stop mechanisms encompassed by claims 4 and 5 were known to be useful in heart-affixing electrodes like Grassi's (Ans. 16). In contrast, Appellants point to no evidence controverting the Examiner's further finding that an ordinary artisan would have considered such mechanisms useful in Grassi's device.

As the preponderance of the evidence supports the Examiner's position, we affirm the Examiner's obviousness rejection of claims 4 and 5.

OBVIOUSNESS --

GRASSI, BISPING, VACHON, AND OCEL

Claim 6 stands rejected as obvious over "either modified Bisping or either modified Grassi as applied to claim 1 above" in view of Ocel or Vachon (Ans. 16).

Claim 6 recites "[t]he distal tip electrode as recited in claim 1, wherein the guiding mechanism includes a groove guide disposed within the mesh screen."

The Examiner finds that "modified Bisping or Grassi discloses the claimed invention with a traveling helix through a mesh screen except for the groove guide" and cites Ocel or Vachon to meet that feature (*id.*). Based on the prior art teachings, the Examiner concludes that an ordinary artisan would have considered it obvious

> to modify the mesh and helical lead as taught by the modified Bisping or Grassi, with a groove guide as taught by Ocel or Vachon since it was known in the art that leads with traveling helixes use a groove guide to provide the predictable results of guiding the helix through the distal end of the lead body/mesh to smoothly guide the helix to exit and enter the lead body.

(*Id.*)

Appellants argue that claim 6 is unobvious for the reasons advanced with respect to claim 1 (App. Br. 16). Moreover, Appellants argue, the Examiner "has provided insufficient motivation to modify the cited reference. Appellant notes that the mere fact that a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination" (*id.* (citing *In re Mills*, 916 F.2d 680; MPEP § 2143.01)).

Appellants' arguments do not persuade us that the Examiner failed to make a prima facie case of obviousness. As discussed above, we are not persuaded that the Examiner's prima facie case was lacking with respect to claim 1.

As to the motivation issue, the Examiner has provided evidence, undisputed by Appellants, that groove guides encompassed by claim 6 were known to be useful in heart-affixing electrodes like those of Grassi and Bisping (Ans. 16). In contrast, Appellants point to no evidence controverting the Examiner's further finding that an ordinary artisan would have considered such mechanisms useful in Grassi's or Bisping's devices.

As the preponderance of the evidence supports the Examiner's position, we affirm the Examiner's obviousness rejection of claim 6.

SUMMARY

We reverse the Examiner's rejection of claims 1-5, 7, 8, and 16-19 under 35 U.S.C. § 103(a) as obvious over Bisping and Dutcher.

However, we affirm the Examiner's rejection of claims 1-5, 7, 8, and 16-19 under 35 U.S.C. § 103(a) as obvious over Bisping, Rockland and Altman.

We also reverse the Examiner's rejection of claims 1, 2, 3, 7, 8, and 16-19 under 35 U.S.C. § 103(a) as obvious Grassi and Dutcher.

However, we affirm the Examiner's rejection of claims 1, 2, 3, 7, 8, and 16-19 under 35 U.S.C. § 103(a) as obvious over Grassi, Rockland and Altman.

We also affirm the Examiner's obviousness rejections of claims 4, 5, and 6.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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